Industry Coalition on 21 CFR Part 11

Consumer Healthcare Products Association
Pharmaceutical Research and Manufacturers of America
National Food Processors Association
Cosmetic, Toiletry, and Fragrance Association
Advanced Medical Technology Association
Generic Pharmaceutical Association
Council for Responsible Nutrition
Animal Health Institute
Medical Device Manufacturers Association
National Electrical Manufacturers Association
Council on Radionuclides and Radiopharmaceuticals

June 14, 2002

Dockets Management Branch
Food and Drug Administration, Room 1061
5630 Fishers Lane
Rockville, MD 20852

Re: **Docket 00D-1541**
Electronic Signatures: Audit Trails

Attached for admission to the above docket is a proposal to address the scope of 21 CFR Part 11. The proposal is submitted on behalf of the Industry Coalition on 21 CFR Part 11, a coalition composed of national trade associations representing industries regulated by the Food and Drug Administration, and thus subject to the conditions set forth in 21 CFR Part 11.

One of the major issues in the effective implementation of 21 CFR Part 11 is that of scope. Many other aspects of the rule hinge on the scope issue. The Coalition hopes that the thoughts expressed in the attached position paper will aid the agency in formulating a reasonable implementation policy and guidance regarding the scope of 21 CFR Part 11.

Cordially yours,

William W. Bradley
Chairman, Steering Committee
Industry Coalition on 21 CFR Part 11

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WB/b

Industry Coalition on 21 CFR Part 11

Proposal to Address the Scope of Part 11

The major stumbling block facing both industry and FDA regarding compliance with and enforcement of Part 11 is the current uncertainty surrounding when an electronic record falls under the regulation. FDA refers to this as the "Scope" issue. The issue has been raised in several meetings between the Industry 21 CFR Part 11 Coalition and FDA, and FDA has assured the affected industries that it will soon publish a draft guidance addressing this issue. The issue appears with significant frequency in various public forums, meetings and trade publications.

One example of a specific problem follows: Regulated industry maintains that documents that are issued and available for use only in approved versions need not have audit trails (which the rule requires must be maintained automatically). Industry met with FDA and had a detailed discussion about this topic. Recent media quotes from FDA staff indicate that at least some FDA staffers do not agree with the concept and maintain that companies must keep audit trails of the work done in drafting final documents. For example, the industry position includes our view that the document approval Standard Operating Procedure and the approved document are "required records" under the device GMP, but the drafts and edits do not need to be retained. Therefore, since these are not "required records, they do not fall under Part 11. The fact that they may be retained does not make them "required records."

GMP Background

When FDA was working with Industry to propose the current Quality System regulation, the question of at what point in the development process the Design Control requirements take effect loomed large in the discussions. Industry expressed its legitimate concerns that documenting a process before it is ready (e.g., before it has taken on a recognizable shape) can be harmful to the development process. Much of the very early creative design work is done very informally, and the personalities of the people doing that work incline them to resist recording it before it they believe it is truly ready to be recorded. The agency believed that a good design control program that documents the decisions made in the process would make it difficult for a design error to propagate through the entire process.

Industry agreed with FDA's fundamental concept, but was concerned that if documentation were required too early in the process, the free flow of creative ideas could be diminished, thus stifling innovation. There are clear benefits to the use of Design Control in an R&D setting that leads directly to manufacturing. Nevertheless, one must keep focused on the ultimate goal, which is the development and production of a commercially viable, safe product. The initial creativity of the designers and engineers is critical to the success of such endeavors.

Ultimately, FDA settled on a compromise position that satisfied regulatory needs and also satisfied industry's needs. Each company must define within its quality system the point at which Design Control becomes effective. This enabled the industry to set the entry point late enough that the design is beyond the point of daily change, yet FDA was comfortable that the information needed to determine how the company approached its design and the justification for major design decisions would be recorded.

While this system has not been perfect—sometimes FDA believes that a company has set the Design Control point too late in the process—it has largely been successful. The industry generally believes that the QS Reg and the QSIT program are a success and good examples of industry-agency cooperation. We believe that Part 11 can and should be handled similarly, that is, include a significant industry role in the determination of a "required records" when not specified in the existing regulations, to be considered for coverage in Part 11.

Proposal

We propose that the FDA Scope guidance should parallel the approach taken in applying Design Control in the Quality System regulation. Simply, we suggest that the company maintaining an electronic record be required to define in its procedures the point at which that record becomes subject to Part 11, in other words, becomes "official." This point would vary with record type as long as it is not specifically called out in the predicate rule. Such records called out in the GMP would be covered in the Part 11 Scope.

For example, some data will become subject to the rule immediately upon collection. This would most particularly apply to quality control laboratory and manufacturing data. Other data, however, including some information collected during clinical trials may need to be converted to electronic form and checked (using dual entry or another accuracy checking method) before it becomes subject to the rule. Edits leading up to approved and final manufacturing procedures would not be subject to the rule, only the final changed and approved document would be.

In addition, there are many documents that are only used in a labeled, released form, most commonly denoted by version numbers, and there are other documents and records for which the point of finality is not obvious. The company would determine when these are final records subject to the records requirements, just as they do now. This would eliminate the ambiguity that now exists, and it would permit companies to tailor their compliance policies to their businesses.

We believe that this last point is very significant. A great deal of the discussion surrounding the "Scope" issue appears to have lost sight of the fact that in most instances, companies have valid business reasons for retaining FDA-required records. Regulatory compliance is only one aspect of record maintenance, and in many cases, it is not the main or strongest driver. We believe that too much of the discussion around this issue has been based on that assumption. When one recognizes this, it becomes clear that it is

in a company's best interest to establish a valid and useful point for finalizing each record.

Much discussion has also seemingly ignored the status of Part 11 in the regulatory hierarchy. Part 11 applies to electronic records required under a "predicate rule," e.g., QSR, GLP, etc. It is not intended to increase the number of records maintained by a regulated company. It is intended to place some requirements on the retention of the records to ensure their usefulness and integrity. Many of the informal interpretations that have been discussed over the past several years would increase significantly the amount of data retained by regulated industries clearly contravening the intent of the rule. We believe that our proposal would limit the amount of retained data to that which is truly needed to satisfy both business and regulatory purposes.

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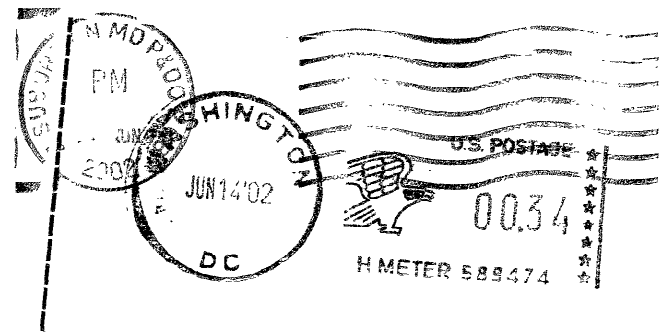

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